

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 04-F-038PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2004/010144	International filing date (day/month/year) 09 July 2004 (09.07.2004)	Priority date (day/month/year) 09 July 2003 (09.07.2003)	
International Patent Classification (IPC) or national classification and IPC C07K 14/47, 16/18, A61P 37/08, A61K 49/00			
Applicant SHIONOGI & CO., LTD.			

This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) Disc 1, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 14 February 2005 (14.02.2005)	Date of completion of this report 31 May 2005 (31.05.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Simile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010144

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ The international application as originally filed/furnished

- ☒ the description:

pages _____ 1-24 _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☒ the claims:

pages _____ 6 _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* 1-5,7-10 received by this Authority on 14 February 2005 (14.02.2005)

pages* _____ received by this Authority on _____

- ☒ the drawings:

pages _____ 1/8-8/8 _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 4-6

because:

☒ the said international application, or the said claims Nos. 4-6 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 4-6 relate to a method for diagnosis of the human body, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1 (iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 4-6 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-3, 7-10	YES
	Claims		NO
Inventive step (IS)	Claims	1-3, 7-10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-3, 7-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Int. J. Legal Med., (2003), Vol. 117, No. 2, p. 90-95

Document 2: Journal of Immunological Methods, (2002), Vol. 270, No. 1, p. 53-62

Document 3: WO 02/100895, A2

Document 1 describes obtaining sweat-specific proteins secreted by the human sweat gland, and preparation of a monoclonal antibody specific to such protein. Specifically, document 1 describes specifically-reacting with the eccrine sweat gland while preparing the antibody G-81 using a protein fraction obtained from sweat using negative ion exchange column chromatography, and the consistency with a dermcidin protein sequence while conducting analysis of the N-terminal amino acid of a protein to which such antibody G-81 is specifically-bound. Also, document 1 describes G-81 bonding to the band of peptides 7kDa, 20, 27 and 33kDa in the sweat through western blot procedure.

The invention of claim 1 of this application amended on February 14, 2005 (hereinafter, claim 1) is an invention relating to "a composition," and differs from the invention described in document 1 in the refinement process wherein a ConA affinity column is used, thus, this examination finds that the components contained in the obtained composition are different from one another.

Also, while document 1 describes that dermcidin protein is an antibiotic peptide; document 1 neither describes nor suggests that the composition relating to claim 1 is "an atopic dermatitis inducer bonding to human IgE antibody *per se* and activating mast cells and basophiles," thus, such composition could not be easily conceived of by a person skilled in the art.

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

** If item 4 in Box No. 1 applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V:

Document 2 describes sweat-derived dermcidin and a partial peptide DCD-1 thereof. Also, document 3 describes isolation of dermcidin from human sweat and gene base sequence that encodes this. Also, page 14 describes obtaining an antibody for dermcidin.

However, neither document 2 or document 3 describes preparing a composition using the refinement process described in claim 1, or suggests that the obtained composition is "an atopic dermatitis inducer bonding to human IgE antibody *per se* and activating mast cells and basophiles."

Based on the above, the inventions of Claims 1 through 3 and 7 through 10 of the present application appear to novel, involve an inventive step and have industrial applicability.

Upon conducting analysis of the N-terminal amino acid to which the such protein such antibody G-81 specifically bonded, and its consistency with a dermcidin protein array.